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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,197	08/07/2001	Neal Gutterson	012176-010810US	2170

20350 7590 03/23/2005

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EXAMINER

BOWMAN, AMY HUDSON

ART UNIT PAPER NUMBER

1635

DATE MAILED: 03/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/924,197	Applicant(s) GUTTERSON ET AL.	
	Examiner Amy H. Bowman	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 and 25-53 is/are pending in the application.
- 4a) Of the above claim(s) 28-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 and 25-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/8/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application/Amendment/Claims

Applicant's response filed 1/6/2005 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 7/2/2004 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

With entry of the amendment filed on 1/6/2005, claims 1-23 and 25-27 are pending in the application. Applicant has canceled claim 24. Claims 28-53 have been withdrawn, as being drawn to non-elected inventions, as a result of the restriction requirement mailed on 10/8/2003.

Response to Arguments--Claim Rejections - 35 USC § 112

Claims 1-27 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention due to the recitation of "substantial" in claims 1 and 15. The rejection is withdrawn due to the amendment filed on 1/6/2005, amending claim 1 to read "at least about 80%".

Claims 1-23 and 26-27 were rejected in the official office action mailed 7/2/04 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for

methods of reducing expression of a target gene in a plant cell, does not reasonably provide enablement for methods of reducing expression of a target gene generally in any organism, particularly a mammalian cell *in vivo*. This rejection is withdrawn due to the amendments to the claims filed on 1/6/05 to specify a plant cell.

New Objections/Rejections

Claim Objections

Claim 15 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 15 is drawn to the method of claim 1, wherein the targeting sequence has substantial identity to a plant target gene. Claim 1 is narrower in scope with regards to identity to a plant target gene, as it specifies "at least about 80%" identity to at least a subsequence of a target gene. Recitation of "substantial identity" in claim 15 does not further limit claim 1.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-23 and 25-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "an inverted repeat of a subsequence of an NOS gene". It is unclear what is meant by "NOS" in claim 1 because NOS could be interpreted in different ways, such as nopaline synthase or nitric oxide synthase. Amendment of claim 1 to read "nopaline synthase (NOS)" would obviate this rejection. Claims 2-23 and 25-27 are rejected due to their dependence on claim 1.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-23 and 25-27 are rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant invention is drawn to a method of reducing expression of a target gene in a plant cell, the method comprising expressing an expression cassette comprising a promoter operably linked to a sense or antisense targeting sequence having at least about 80% identity to at least a subsequence of the target gene, wherein

the subsequence has a length of at least about 25 nucleotides, and an inverted repeat of a subsequence of a NOS gene, wherein the inverted repeat is at least about 30 base pairs in length and is heterologous to the targeting sequence, thereby reducing expression of the target gene.

The instant inverted repeat has not been described in a way that one of ordinary skill in the art would be able to readily envisage the claimed invention. The specification teaches that each element of the inverted repeat is about 15 to about 500 base pairs in length (see page 5, lines 12-13). Additionally, the instant specification teaches a 260 base pair structure that has an inverted repeat. However, the specification does not show which portion of the 260 base pair sequence actually is the inverted repeat region.

Mitra et al. teach that the inverted repeat from the NOS gene is 16 base pairs in length and is composed of two 8 base pair repeat regions that have been shown to be important for promoter function (see abstract).

Applicant has not described any inverted repeats greater than a total of 16 base pairs combined between two repeat elements. Although the 260 base pair sequence disclosed in the specification is taught to contain an inverted repeat, the specification does not disclose which portion of the sequence is actually the inverted repeat elements rather than the middle region between the inverted repeats. Therefore, the state of the art demonstrates that the inverted repeat region is actually 16 base pairs without the middle region, which is not actually a part of the inverted repeat sequence. The instant specification has not demonstrated or taught any inverted repeat of the NOS gene that comprises any more than a 16 base pair inverted repeat region (the result of two 8 base

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pair elements). Therefore, one skilled in the art would recognize that the NOS gene does not have an inverted repeat greater than 16 base pairs in length.

Without description of the which region of the instant sequence is actually the inverted repeat, one of skill in the art would not have been able to recognize what the claimed structure actually encompasses.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

MPEP 2163 states in part, "An adequate written description of a chemical invention also requires a precise definition, such as by structure, formula, chemical name, or physical properties, and not merely a wish or plan for obtaining the chemical invention claimed. See, e.g., *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 927, 69 USPQ2d 1886, 1894-95 (Fed. Cir. 2004)

Thus, the instantly claimed invention cannot be said to have been adequately described in a way that would convey with reasonable clarity to those skilled in the art that, as of the filling date sought, applicant was in possession of the claimed invention because the specification does not provide a description or any specific embodiments of an inverted repeat of a NOS gene that is greater than 16 base pairs in length to clearly describe the instantly claimed structure.

This action is FINAL. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy H. Bowman whose telephone number is 571-272-0755. The examiner can normally be reached on Mon-Fri 7:30 am – 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Amy H. Bowman
Examiner
Art Unit 1635

A handwritten signature in black ink, appearing to read 'Andrew Wang', is positioned above the printed name.

ANDREW WANG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600